

### § 118.3

### 21 CFR Ch. I (4–1–10 Edition)

(1) If any of your eggs that are produced at a particular farm do not receive a treatment as defined in §118.3, you must comply with all of the requirements of this part for egg production on that farm.

(2) If all of your eggs that are produced at the particular farm receive a treatment as defined in §118.3, you must comply only with the refrigeration requirements in §118.4(e) for production of eggs on that farm and with the registration requirements in §118.11.

(b) If you transport or hold shell eggs for shell egg processing or egg products facilities, you must comply with the refrigeration requirements in §118.4(e). This section applies only to eggs from farms with 3,000 or more laying hens.

#### § 118.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the FFDCA) (21 U.S.C. 321) are applicable to such terms when used in this part, except where they are redefined in this part. The following definitions also apply:

*Biosecurity* means a program, including the limiting of visitors on the farm and in poultry houses, maintaining personnel and equipment practices that will protect against cross contamination from one poultry house to another, preventing stray poultry, wild birds, cats, and other animals from entering poultry houses, and not allowing employees to keep birds at home, to ensure that there is no introduction or transfer of *Salmonella* Enteritidis (SE) onto a farm or among poultry houses.

*Egg products facility* means a USDA-inspected egg products plant where liquid, frozen, and/or dried egg products are produced.

*Farm* means all poultry houses and grounds immediately surrounding the poultry houses covered under a single biosecurity program.

*Flock* means all laying hens within one poultry house.

*Group* means all laying hens of the same age within one poultry house.

*Induced molting* means molting that is artificially initiated.

*Laying cycle* means the period of time that a hen begins to produce eggs until

it undergoes induced molting or is permanently taken out of production and the period of time that a hen produces eggs between successive induced molting periods or between induced molting and the time that the hen is permanently taken out of production.

*Molting* means a life stage during which hens stop laying eggs and shed their feathers.

*Pest* means any objectionable animal including, but not limited to, rodents, flies, and larvae.

*Positive flock* means a flock that has had an egg test that was positive for SE. A flock is considered positive until that flock meets the egg testing requirements in §118.6(c) to return to table egg production.

*Positive poultry house* means a poultry house from which there has been an environmental test that was positive for SE at any time during the life of a group in the poultry house until that house is cleaned and disinfected according to §118.4(d).

*Poultry house* means a building, other structure, or separate section within a structure used to house poultry. For structures comprising more than one section containing poultry, each section that is separated from the other sections is considered a separate house.

*Producer* means a person who owns and/or operates a poultry house containing laying hens which produce shell eggs for human consumption.

*Shell egg* (or egg) means the egg of the domesticated chicken.

*Shell egg processing facility* means a facility that processes (e.g., washes, grades, packs) shell eggs for the table egg market.

*Treatment* (or treated) means a technology or process that achieves at least a 5-log destruction of SE for shell eggs, or the processing of egg products in accordance with the Egg Products Inspection Act.

#### § 118.4 *Salmonella* Enteritidis (SE) prevention measures.

You must follow the SE prevention measures set forth in this section. In addition, you must have and implement a written SE prevention plan that is specific to each farm where you produce eggs and that includes, at a

minimum, the following SE prevention measures:

(a) *Pullets*. You must procure pullets that are SE monitored or raise pullets under SE monitored conditions. "SE monitored" means the pullets are raised under SE control conditions that prevent SE, including:

(1) *Procurement of chicks*. Chicks are procured from SE-monitored breeder flocks that meet the National Poultry Improvement Plan's standards for "U.S. S. Enteritidis Clean" status (9 CFR 145.23(d)) or equivalent standard;

(2) *Environmental testing*. (i) The pullet environment is tested for SE when pullets are 14 to 16 weeks of age;

(ii) If the environmental test required in paragraph (a)(2)(i) of this section is negative, you do not need to perform any additional testing of those birds or their environment until the environmental test at 40 to 45 weeks of age specified in § 118.5(a); and

(iii) If the environmental test required in paragraph (a)(2)(i) of this section is positive, you must begin egg testing, as specified in § 118.6, within 2 weeks of the start of egg laying.

(3) *Cleaning and disinfection*. If the environmental test required in paragraph (a)(2) of this section is positive, the pullet environment is cleaned and disinfected, to include:

(i) Removal of all visible manure;

(ii) Dry cleaning the positive pullet house to remove dust, feathers, and old feed; and

(iii) Following cleaning, disinfection of the positive pullet house with spray, aerosol, fumigation, or another appropriate disinfection method.

(b) *Biosecurity*. As part of this program, you must take steps to ensure that there is no introduction or transfer of SE into or among poultry houses. Among such biosecurity measures you must, at a minimum:

(1) Limit visitors on the farm and in the poultry houses;

(2) Maintain practices that will protect against cross contamination when equipment is moved among poultry houses;

(3) Maintain practices that will protect against cross contamination when persons move between poultry houses;

(4) Prevent stray poultry, wild birds, cats, and other animals from entering poultry houses; and

(5) Not allow employees to keep birds at home.

(c) *Rodents, flies, and other pest control*. As part of this program, you must:

(1) Monitor for rodents by visual inspection and mechanical traps or glueboards or another appropriate monitoring method and, when monitoring indicates unacceptable rodent activity within a poultry house, use appropriate methods to achieve satisfactory rodent control;

(2) Monitor for flies by spot cards, Scudder grills, or sticky traps or another appropriate monitoring method and, when monitoring indicates unacceptable fly activity within a poultry house, use appropriate methods to achieve satisfactory fly control.

(3) Remove debris within a poultry house and vegetation and debris outside a poultry house that may provide harborage for pests.

(d) *Cleaning and disinfection*. You must clean and disinfect the poultry house according to these procedures before new laying hens are added to the house, if you have had an environmental test or an egg test that was positive for SE at any point during the life of a flock that was housed in the poultry house prior to depopulation. As part of the cleaning and disinfection procedures, you must:

(1) Remove all visible manure;

(2) Dry clean the positive poultry house to remove dust, feathers, and old feed; and

(3) Following cleaning, disinfect the positive poultry house with spray, aerosol, fumigation, or another appropriate disinfection method.

(e) *Refrigeration*. You must hold and transport eggs at or below 45 °F ambient temperature beginning 36 hours after time of lay. If the eggs are to be processed as table eggs and are not processed for the ultimate consumer within 36 hours from the time of lay and, therefore, are held and transported as required at or below 45 °F ambient temperature, then you may then hold them at room temperature for no more than 36 hours just prior to processing to allow an equilibration step to temper the eggs.